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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,835	05/04/2005	Markus Krumme	RO-4037US (#90568)	8149
D Peter Hochberg 1940 East 6th Street 6th Floor Cleveland, OH 44114	7590 06/04/2009		EXAMINER ORWIG, KEVIN S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,835	Applicant(s) KRUMME, MARKUS
	Examiner Kevin S. Orwig	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 February 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) 10-12, 16, 17 and 20-22 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-9, 13-15, 18, and 19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on May 4, 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 5/4/05, 6/27/07

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of the Claims

Claims 1-22 are currently pending. Claims 1-9, 13-15, 18, and 19 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claims 10-12, 16, 17, and 20-22 are withdrawn from consideration.

Election/Restrictions

Applicant's election of Group I (claims 1-15 and 18-21) in the reply filed on Feb. 26, 2009 is acknowledged. In response to applicant's election, Group II (claims 16, 17, and 22) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have elected Group I with traverse.

The traversal is on the ground(s) that the cited reference (Kizawa) does not teach a hydrophilic mucoadhesive polymer dispersed in a polyvinyl alcohol matrix. The traversal is not found persuasive. Applicant's comments regarding Kizawa are acknowledged. However Kizawa teaches hydrophile mucoadhesive polymers such as carboxymethyl cellulose and salts thereof, which may be combined with PVA (col. 3, line 8). Thus, the instant inventions still lack unity and the restriction requirement is maintained, particularly in view of applicant's species election and the references and rejections set forth below.

Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

In the response of Feb. 26, 2009, applicants elected the following species:

Hydrophilic, mucoadhesive polymer: poly(methyl vinyl ether maleic anhydride)

Number of layers: 2 (two) layers

Claim 10 is withdrawn from consideration as being drawn to a nonelected species as it requires at least three layers. Claims 11, 12, 20, and 21 are also withdrawn as they either directly or indirectly depend from claim 10 and also require more than two layers in the preparation.

Thus, claims 1-9, 13-15, and 18-19 will be examined further on the merits.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided or were not provided in English.

Specification

The substitute specification filed May 4, 2005 is acknowledged and has been entered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02, particularly 602.06. The oath or declaration is defective because it is filed in a foreign language and is not accompanied

by an English translation. Applicant is directed to 37 CFR 1.69 regarding foreign language oaths (see below).

§ 1.69 Foreign language oaths and declarations.

(a) Whenever an individual making an oath or declaration cannot understand English, the oath or declaration must be in a language that such individual can understand and shall state that such individual understands the content of any documents to which the oath or declaration relates.

(b) Unless the text of any oath or declaration in a language other than English is in a form provided by the Patent and Trademark Office or in accordance with PCT Rule 4.17(iv), it must be accompanied by an English translation together with a statement that the translation is accurate, except that in the case of an oath or declaration filed under § 1.63, the translation may be filed in the Office no later than two months from the date applicant is notified to file the translation.

The time period for filing the English translation is TWO MONTHS from the mailing date of this Office Action. Note that this is a separate time period from the time to reply to the Office Action.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite in the recitation "substantially comprises" in line two of the claim. While the mucoadhesive layer can clearly comprise the polymer mixture in claim 1, it is unclear what limitations, if any, the term "substantially" is intended to convey. The polymer mixture is either included in the mucoadhesive layer or it is not. The term "substantially" is not defined nor discussed at all in the specification. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and the metes and bounds of this claim are indefinite.

Claim 7 is indefinite in the recitation "chemically allied" in line two of the claim. This phrase is unclear and does not have a generally recognized standard definition in the art. Further, no definition or discussion of this phrase is presented in the specification. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention and the metes and bounds of this claim are indefinite.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Nov. 24, 2003, the filing date of PCT application PCT/EP03/12272 to which the instant national stage 371 application claims priority.

Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the German application was filed with the USPTO on

May 4, 2005. In the case that an intervening reference is applied in a rejection, applicants will be entitled to the foreign priority date for the purpose of overcoming the date of the reference, provided that a certified English language translation is supplied and it is determined that the corresponding foreign application supports the claims in the manner required by 35 U.S.C. 112, first paragraph. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7-9, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over YUKIMATSU (U.S. 4,740,365; Issued Apr. 26, 1988).

1. Yukimatsu discloses a two-layer sustained release preparation for application to mucous membranes in the oral cavity (abstract; col. 2, lines 14-16; col. 3, lines 22-54). The preparations have a film-like shape (col. 3, lines 16-21; col. 4, lines 40-42). Yukimatsu teaches that a first layer comprises an active ingredient and one or more polymers including polyvinyl alcohol and a copolymer of maleic anhydride and methyl vinyl ether (i.e. poly(methyl vinyl ether maleic anhydride)) (col. 3, lines 32-37; Example 7). Yukimatsu teaches that a second layer (i.e. a backing layer) comprises one or more polyacrylic acid (i.e. polyacrylate) polymers (col. 3, lines 49-51). Thus, Yukimatsu teaches each element of instant claim 1. The only difference between Yukimatsu and the instant claims is that Yukimatsu does not embody the claimed invention sufficiently to be considered anticipatory.

2. Regarding the limitations of solubility and swelling, these characteristics are properties inherent to the particular polymers. Yukimatsu addresses the same problem in the art, namely providing sustained release mucoadhesive preparations with sufficient adhesion in the oral cavity. Since the purpose of Yukimatsu's invention is the very same as that instantly claimed and since Yukimatsu discloses the very same polymers for this purpose, it is reasonable that the preparations would have the same

characteristics. This interpretation is consistent with the prior art disclosure since it is clear that the preparations are intended to remain intact in the aqueous environment of the oral cavity for a long period of time, for example 4 to 24 hours (i.e. they are insoluble or poorly soluble in the oral aqueous media) and that the preparations are swollen by saliva (col. 6, lines 33-41). Thus, in the absence of evidence to the contrary, Yukimatsu's mucoadhesive layer swells in aqueous media, but is insoluble or poorly soluble in the aqueous media. Furthermore, the polyacrylate-containing layer would necessarily reduce the permeation of water and the diffusion of active substance relative to the other layer, as in the instant application. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

3. Yukimatsu teaches that the desired sustained-release properties of the active ingredient and the feel of the preparation can be modulated by adjusting the ratio of the polymer components in the composition (col. 2, line 63 to col. 3, line 8; col. 6, lines 51-68). Thus, by selecting the appropriate combination of polymers, Yukimatsu clearly teaches that any of the disclosed polymers is suitable to achieve the purpose of the invention with no more than routine experimentation. It is noted that the MPEP states that the selection of known materials based on their suitability for their intended uses is

prima facie obvious. See MPEP § 2144.07. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

4. The issue of indefiniteness regarding claim 2 has been presented above. For the purposes of this rejection, the claim has been interpreted to mean the mucoadhesive layer comprises said polymer mixture.

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use poly(methyl vinyl ether maleic anhydride) with polyvinyl alcohol, to provide a suitable mucoadhesive layer. One would have been motivated to do so with a high expectation of success since Yukimatsu teaches a two-layer mucoadhesive composition wherein the first layer may comprise polyvinyl alcohol and a copolymer of maleic anhydride and methyl vinyl ether and the second layer comprises polyacrylates. Thus, Yukimatsu renders claims 1-3, 8, 9, and 19 obvious.

6. The issue of indefiniteness regarding claim 7 has been presented above. For the purposes of this rejection, the claim has been interpreted to mean that at least one identical polymer is required between the two layers. Yukimatsu teaches that the adjacent layers of the preparation may comprise at least one identical polymer (col. 3, lines 32-54), rendering claim 7 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA)

1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 4-6, 13-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yukimatsu as applied to claims 1-3, 7-9, and 19 above, and further in view of RUPPRECHT (WO 01/03917, Published Jan. 18, 2001) as evidenced by U.S. 2002/0142036 (hereinafter '036).

7. Since the WO document to Rupprecht is in German, U.S. 2002/0142036, the U.S. continuation of WO 01/03917 is relied upon herein as an English language equivalent. Paragraph numbers regarding Rupprecht refer to '036.

8. The teachings of Yukimatsu are presented *supra*. Yukimatsu teaches that crosslinked polymers can be used in either of the two layers (col. 2, lines 50-55; col. 4, lines 1-5). Furthermore, one would be motivated to select crosslinked polymers for the mucoadhesive layer in light of Rupprecht.

9. Rupprecht discloses transmucosal multi-layered films made of film-forming polymers (abstract). The films contain an active substance containing layer and a covering (i.e. backing) layer. The active substance layer may be produced from suitable film-forming water-soluble polymers that are crosslinked (paragraphs [0019] and

[0023]). Rupprecht teaches that the ratio of crosslinking agent (i.e. the amount of crosslinking) may be varied to optimize the film properties such as the active substance release properties of the film (paragraphs [0021] and [0023]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select a cross-linked polymer as taught by Yukimatsu. One would have been motivated to do so with a high expectation of success since Yukimatsu teaches the use of crosslinked polymers in either of the two layers and since Rupprecht teaches that the amount of crosslinking can be adjusted to optimize the release properties of the film. Thus, the combination of Yukimatsu and Rupprecht renders claim 4 obvious.

10. Moreover, Rupprecht teaches that preferred cover (i.e. backing) layer materials are films formed from mixtures of polymers and teaches that Eudragit E (i.e. a neutralized polymethyl methacrylate according to paragraph [0027] of the instant application) is a suitable preferred cover layer material (paragraph [0014]). Rupprecht also teaches that mixtures of polymers may be used in the backing layer to optimize the properties of this layer, which Rupprecht teaches include mechanical stabilization of the film, diffusion prevention of the active substance, unidirectional release of the active substance, and adjustment of the sustained release profile of the active agent (paragraphs [0010], [0015], and [0024]-[0026]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to select a neutralized polymethyl methacrylate as a component of the backing layer. One would have been motivated to do so with a high expectation of success

since Yukimatsu teaches the use of polyacrylates in the backing layer and since Rupprecht teaches that mixtures of polymers can be used to optimize the release properties of the backing layer and teaches Eudragit E as a preferred component of the backing layer. Thus, the combination of Yukimatsu and Rupprecht renders claim 5 obvious.

11. Rupprecht teaches that the function of the backing layer can be expanded by incorporating colored pigments or other auxiliary substances into the layer to optimize its properties [0016]; claim 10). Yukimatsu also teaches the use of conventional additives in the backing layer (col. 3, lines 53-54). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate pigments into the cover layer as taught by Rupprecht. One would have been motivated to do so with a high expectation of success since Yukimatsu teaches the use of conventional additives in this layer and since Rupprecht teaches that colored pigments can be added to optimize the properties of use. A skilled artisan would have understood the advantages of incorporating a colored pigment, for example to improve consumer appeal. Thus, the combination of Yukimatsu and Rupprecht renders claim 6 obvious.

12. Yukimatsu teaches that the active agent along with the polymer components is dissolved in a solvent that is dried to form the film-like preparation wherein the active agent is in a solid solution with the polymer (col. 3, lines 18-21; col. 5, lines 36-42; Examples 11 and 15). Furthermore, Rupprecht explicitly teaches that incorporation of the active agent is preferably carried out by dissolving the active substance(s) or, if

necessary, emulsifying and/or suspending the active substance(s) in the form of liquid or solid particles in solutions of the crosslinking agent (paragraph [0051]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to incorporate the active substance in a form such as dissolved, suspended, or emulsified. The combination of Yukimatsu and Rupprecht renders claim 13 obvious.

13. Yukimatsu teaches that the active agent may be present in both layers (col. 3, lines 32-54), but does not explicitly teach the use of a concentration gradient. However, Rupprecht teaches that the layers of the film preferably contain the same active substance, each layer having a different respective release profile. Rupprecht teaches that the substance containing layers may exhibit horizontal and/or vertical gradients of the active substance (paragraphs [0024]-[0025]; claim 1). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to prepare a transmucosal film wherein each layer contained the same active substance as taught by Yukimatsu at different concentrations as taught by Rupprecht. One would have been motivated to do so with a high expectation of success since Yukimatsu teaches a two-layer mucoadhesive composition wherein each layer comprises an active substance and since Rupprecht teaches that formulating the active substances in concentration gradients is preferred. A skilled artisan would have understood the advantages of using a gradient of active agent(s), for example to adjust the sustained release profile of the film. Thus, the combination of Yukimatsu and Rupprecht renders claim 14 obvious.

14. According to the instant specification, diffusion and permeation properties can be modified by varying the pigment content and/or by admixing suitable polymers (e.g. cellulose compounds) (see paragraph [0041]). Since Yukimatsu teaches the inclusion of a variety of polymers (including cellulose compounds) and conventional additives in both layers (col. 3, lines 32-54; col. 4, lines 16-26), and since Rupprecht teaches the use of both pigments and various polymers (including cellulose compounds) these additives would necessarily modify the solubility and diffusion coefficient of the active substance. Yukimatsu and Rupprecht render claim 15 obvious.

15. Yukimatsu teaches the use of polyacrylic acid (i.e. polyacrylates in an aqueous environment at physiological pH) in the cover layer (i.e. layer II), but does not explicitly embody polyacrylates in both layers. However, Rupprecht teaches that both the active substance layer and the cover layer can preferably be based on anionic polymers such as polyacrylates (paragraphs [0013], [0014], [0022], [0023], and [0047]; claims 8 and 11). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include polyacrylates (or polyacrylic acid) in both layers of the dosage form. One would have been motivated to do so with a high expectation of success since Yukimatsu teaches that the desired sustained-release of the active ingredient can be modified by using the combination of various polymers, and since Rupprecht teaches that polyacrylates are preferred base polymers for both layers. Thus, in optimizing the formulation of the layers based on Yukimatsu's teachings, Rupprecht would guide one to include polyacrylates in both layers. Thus, the combination of Yukimatsu and Rupprecht renders claim 18 obvious.

Claims 1-9, 13-15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over RAULT (U.S. 6,242,004, Issued Jun. 5, 2001) in view of RUPPRECHT (WO 01/03917, Published Jan. 18, 2001) as evidenced by U.S. 2002/0142036 (hereinafter '036).

16. Rault discloses multilayered bioadhesive compounds for transmucosal administration of active substances (abstract; col. 1, lines 3-5 and 49-51). Rault teaches that the compositions are tablets that have a flat or oblong shape (i.e. film-shaped) to ensure the best prolonged maintenance of the form on its site of action (col. 7, lines 31-34). Advantageously, the bioadhesive layer Rault's compositions is composed of a maleic anhydride polymer, preferably a copolymer of methylvinylether and maleic anhydride (i.e. poly(methyl vinyl ether maleic anhydride) (col. 2, lines 38-42). Rault teaches that in an advantageous embodiment, the bioadhesive material (i.e. copolymer of methylvinylether and maleic anhydride) is mixed with at least one swelling agent including polyvinyl alcohol (col. 2, lines 63; col. 3, lines 6-7). Rault teaches that the bioadhesive matrix may be crosslinked (col. 2, lines 57-65; col. 3, line 20). Rault teaches that it is advantageous to include a barrier (i.e. backing) layer as a barrier to the diffusion of active principle and to the penetration of water/biological fluid (col. 2, lines 17-21). Rault teaches that the barrier layer(s) are formed from the active principle and a swelling agent (which may be a polyacrylate) (col. 2, lines 60-61). Thus, the only difference between Rault and the instant claims is that Rault does not embody the specific combination of the exact polymer species claimed in the instant invention sufficiently to be considered anticipatory.

17. However, Rupprecht discloses transmucosal multi-layered films made of film-forming polymers (abstract). The films contain an active substance containing layer and a covering (i.e. backing) layer. Moreover, Rupprecht teaches that preferred cover (i.e. backing) layer materials are films formed from mixtures of polymers and teaches that Eudragit E (i.e. a neutralized polymethyl methacrylate according to paragraph [0027] of the instant application) is a suitable preferred cover layer material (paragraph [0014]). Rupprecht also teaches that mixtures of polymers may be used in the backing layer to optimize the properties of this layer, which Rupprecht teaches include mechanical stabilization of the film, diffusion prevention of the active substance, unidirectional release of the active substance, and adjustment of the sustained release profile of the active agent (paragraphs [0010], [0015], and [0024]-[0026]).

18. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use polyacrylates in the backing layer. One would have been motivated to do so with a high expectation of success since Rault teaches the use of polyacrylates, and since Rupprecht teaches that polyacrylates are preferred base polymers for the backing layer. It is noted that the MPEP states that the selection of known materials based on their suitability for their intended uses is *prima facie* obvious. See MPEP § 2144.07. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.). Thus, the combination of Rault and Rupprecht renders claims 1-9, 13-15, 18, and 19 obvious.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 11/408,958

Claims 1-9, 13-15, 18, and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 7-9 of copending Application No. 11/408,958 in view of Rault and Rupprecht. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '958 claims renders obvious that of the instant claims. The difference between the two claim sets is that the '958 claims recite rapid release from one layer and slow release from another layer. However, this element, and thus the entire scope of the instant claims is rendered obvious since, the instant claim 14 recites at least two layers containing an active substance at different concentrations, which would meet the limitations of the '958 claims. Thus, the instant claims represent an obvious variation of the '958 claims.

Claims 1-9, 13-15, 18, and 19 are directed to an invention not patentably distinct from claims 1-4, and 7-9 of commonly assigned 11/408,958. Specifically, see above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/408,958, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

Claims 1-9, 13-15, and 18-19 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

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